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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,348	08/15/2003	Keith K. Daellenbach	BJT 332B	1593

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EXAMINER

MAIORINO, ROZ

ART UNIT PAPER NUMBER

3763

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/642,348

Applicant(s)

DAELLENBACH, KEITH K.

Examiner

Roz Maiorino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3-05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Double Patenting***

1. Claims 1-11, 13-20 provisionally rejected under the judicially created doctrine of double patenting over claim 1-7, 9-25 of copending Application No. 10/085564. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: applicant's current claims are a broad version of the above mentioned application.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-6, 8-11, 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. US 5833632 to Jacobsen et al.

Jacobsen teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effectors; and an ejection mechanism adapted to eject the fluid form the fluid reservoir through the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal section ; wherein some of the orifices are located the distal section.

1. Claims 1-6, 8-11, 13-20 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. US 6623449 to Paskar.

Paskar teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end

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effectors; and an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal section ; wherein some of the orifices are located the distal section. (figures 12, 10, 15, 16, 21A-22C)

2. Claims 1-6, 8-11, 13-20 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No.6344027 to Goll.

Goll teaches a needle less jet injection device use for the heart with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effector ; and an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effectors and out of the orifice with sufficient pressure to penetrate the organ ; the end effectors includes a straight shaft section and a distal section (figure 6E) ; wherein some of the orifices are located the distal section. the outer diameter of the end effector is between 0.100 and 0.300 inches (Col.3, lines 15-25)

3. Claims 1-6, 8-11, 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. US 5997525 to March et al.

March teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effector; and an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal. (Figures 3-5)

4. Claims 1-6, 8-11, 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. US 5489269 to Aldrich et al

March teaches a needle less jet injection device with a rigid end effectors including a plurality of orifices; a fluid reservoir in fluid communication with the end effector; and an ejection mechanism adapted to eject the fluid form the fluid reservoir through the end effectors and out of the orifice with sufficient pressure to penetrate the organ; the end effectors includes a straight shaft section and a distal. (figures 1-3)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6344027 to Goll or US Patent No. US 5997525 to March et al. Or US Patent no. 5489269 to Aldrich et al or US Patent No. US 5833632 to Jacobsen et al or US Patent No. US 6623449 to Paskar.

As mentioned above Paskar, Goll, Aldrich, March and Jacobsen all teach the applicant invention however none of the above prior art teach the use of ethanol with their apparatus. All of the above inventors do use their apparatus for some type of medication or fluid therefore it would have been obvious to one having ordinary skill in the art to have used the above prior art for the use of introduction of ethanol because of

the above apparatus can be used for medication or fluid introduction into an organ and hence are capable for carrying ethanol.

### ***Response to Arguments***

Applicant's arguments filed 3/24/2005 have been fully considered but they are not persuasive.

In response to applicant's argument that the ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effectors and out of the injection orifice with sufficient pressure to penetrate the prostate gland while preserving functionality of the prostate gland, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Applicant also alleges that Goll does not teach blunt distal end, however on col. 6 lines 47-55 Goll discloses injection catheter may have a blunt distal end.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RM

A handwritten signature, possibly reading 'RM', in black ink.A handwritten signature in black ink, likely belonging to Nicholas D. Lucchesi.

**NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700**